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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,703

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

01/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/772,703

Applicant(s)

COLONE, WILLIAM M.

Examiner

Walter B. Aughenbaugh

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42, 46, 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42, 46, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's Request for Reconsideration filed October 12, 2007 has been received and considered by Examiner.

WITHDRAWN REJECTION

2. The 35 U.S.C. 102 rejection of claims 42 and 50 made of record in paragraph 8 of the previous Office Action mailed July 27, 2007 has been withdrawn due Applicant's reconsideration.

NEW REJECTIONS

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "highly crystalline" in claim 50 is a relative term which renders the claim indefinite. The term "highly crystalline" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

6. Claims 42 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosse et al. (USPN 5,321,109) or Bosse et al. (USPN 5,468,138).

In regard to claim 42, Bosse et al. teach a radially expandable tube consisting of extruded expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils, where the tube is pre-dilated (expanded by stretching to a desired dimension) (col. 1, lines 13-20).

Bosse et al. fail to explicitly teach the claimed radial expansion ratio.

However, Bosse et al. teach that the tube is then sintered after pre-dilatation (heated to approximately 375°C). Since the expanded tube will contract back to its pre-expanded shape (col. 1, lines 39-50) if it is not held to its expanded dimensions (col. 1, lines 39-50), the tube disclosed by Bosse et al. will contract back to its pre-expanded shape when it is not held to its expanded dimensions, so the tube disclosed by Bosse et al., upon contraction of the tube, has the claimed radial expansion ratio.

Furthermore or alternatively, in regard to the claimed radial expansion ratio, “the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid

that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.” *Id.* MPEP 2112.

In regard to claim 50, Bosse et al. teaches a highly crystalline (col. 1, lines 44-47) porous polytetrafluoroethylene tube where the tube is pre-dilated (expanded by stretching to a desired dimension) (col. 1, lines 13-20). Bosse et al. teach that the tube is then sintered after pre-dilatation (heated to approximately 375°C).

Bosse et al. fail to explicitly teach the claimed radial expansion ratio.

However, Bosse et al. teach that the tube is then sintered after pre-dilatation (heated to approximately 375°C). Since the expanded tube will contract back to its pre-expanded shape (col. 1, lines 39-50) if it is not held to its expanded dimensions (col. 1, lines 39-50), the tube disclosed by Bosse et al. will contract back to its pre-expanded shape when it is not held to its expanded dimensions, so the tube disclosed by Bosse et al., upon contraction of the tube, has the claimed radial expansion ratio.

Furthermore or alternatively, in regard to the claimed radial expansion ratio, “the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA

1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.” *Id.* MPEP 2112.

7. Claims 46 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosse et al. (USPN 5,321,109) (or Bosse et al., USPN 5,468,138) in view of Marin et al. (US 5,618,300).

Bosse et al. teach the tube as discussed above in regard to claims 42 and 50.

Bosse et al. fail to teach that the tube is attached to an expandable stent.

Marin et al., however, disclose a graft-stent complex comprising an expandable polytetrafluoroethylene graft (item 46) that is sutured (therefore, attached) to a pair of expandable stents (items 48a and 48b) (col. 4, lines 43-65 and Fig. 1). Therefore, one of ordinary skill in the art would have recognized to have attached the pair of expandable stents of Marin et al. to the tube of Bosse et al. and to have used the resulting structure as the graft-stent complex of Marin et al. since it is well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the pair of expandable stents of Marin et al. to the tube of Bosse et al. and to have used the resulting structure as the graft-stent complex of

Marin et al. since it is well known to attach a pair of expandable stents to a expandable polytetrafluoroethylene tube to form a graft-stent complex as taught by Marin et al.

8. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boatman et al. (USPN 5,632,771).

In regard to claims 50 and 51, Boatman et al. teach the claimed product (stent, col. 4, lines 48-53, col. 2, line 55-col. 3, line 7 and col. 7, lines 26-31), except Boatman et al. fail to teach that the product has a radial expansion ratio of 1.0. The PTFE claimed by Applicant falls within the scope of the PTFE taught by Boatman et al. Boatman et al., however, disclose that the desired radial expansion ratio may be achieved by appropriately selecting the width of the cell along the reinforcing member and the height or extension of the cell from the reinforcing member (col. 5, line 60-col. 6, line 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the width of the cell along the reinforcing member and the height or extension of the cell from the reinforcing member in order to achieve the desired radial expansion ratio, depending on the particular desired end result, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results. MPEP 2144.05 II.B.

Response to Arguments

9. Applicant's arguments presented on pages 2-4 of the Request for Reconsideration regarding the 35 U.S.C. 102 rejection (to the extent these arguments now apply to the 35 U.S.C. 103 rejection of claims 42 and 50) have been fully considered but are not persuasive. It is Examiner's position that tubes (and tubular films) fall within the discussion of Bosse in col. 1 of Bosse. It is Examiner's position that resulting (col. 1, line

18 of Bosse '109) merely refers to the "tube or film" after the "tube or film" is "stretch[ed] and expand[ed]" (col. 1, lines 6-12 of Bosse '109).

10. Applicant's arguments presented on page 4 of the Request for Reconsideration regarding the 35 U.S.C. 103 rejection of claims 46 and 51 have been fully considered but are not persuasive. Applicant's arguments depend entirely upon Applicant's arguments regarding the rejection of claims 42 and 50, which have been addressed above in this Office Action.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is (571) 272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris, can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter B. Aughenbaugh
12/21/07

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12/21/07